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EXAMINER

PENG, KUO LIANG

ART UNIT PAPER NUMBER

1712

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,742

Applicant(s)

GUNATILLAKE ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/04 Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 133-136, 147-151 and 157 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 95-98 and 153 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 88, 105-108, 114, 137-140, 142-144 and 152 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Disposition of Claims: Claims pending in the application are 77-80,83,84,86,88,89,92,93,95-98,101,102,105-111,113,114,116-124,127-140,142-144 and 147-157.

Continuation of Disposition of Claims: Claims rejected are 77-80,83,84,86,88,89,92,93,101,102,105-111,113,114,116-124,127-132,137-140,142-144,152 and 154-156.

Continuation of Attachment(s) 6). Other: English translation of JP 63-179916 .

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DETAILED ACTION

1. The Applicants' amendment filed on March 15, 2004 was received. Claims 77, 84, 86, 88-89, 92, 95-96, 101, 103, 116-117, 119, 127-129, 131-133, 136-137, 143 and 151 are amended. Claims 81-82, 85, 87, 90-91, 94, 99-100, 103-104, 112, 115, 125-126, 141 and 145-147 are deleted. Claims 153-157 are added. Claims 148-150 are withdrawn.
2. It is noted that Claims 133-136, 147 and 151 have been withdrawn from further consideration as indicated in the previous Office action. Newly added Claim 157 is directed to a process for preparing a shape memory polymer, and should belong to Group II. Therefore, Claim 157 is withdrawn from further consideration. Now, Claims 77-80, 83-84, 86, 88-89, 92-93, 95-98, 101-102, 105-111, 113-114, 116-124, 127-140, 142-144 and 147-157 are pending. Claims 133-136, 147-151 and 157 are withdrawn from further consideration.
3. The rejections under 35 USC 102(b) as being anticipated by and/or under 35 USC 103(a) as being unpatentable over Hayashi832 (US 5 139 832), Hayashi591 (US 5 049 591), Pudleiner (US 5 430 121), Meijs858 (US 5 393 858) and Hideyuki (JP 04-248826) are removed.
4. The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action (Paper No. 11).

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Claim Objections

5. Claims 88, 105-108, 114, 137-140, 142-144 and 152 are objected to because of the following informalities:

In Claim 88 (line 2), should "(III)" be -- (II) --?

In Claim 114 (line 2), should "claim 112" be -- claim 77 --?

In Claim 137 (line 3), should "claim 125" be -- claim 154 --?

Claims 137-140 and 142-144 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the embodiment of combining the limitations recited in Claim 77 and Claim 125 [154] in the Claims 137-140 and 142-144 has not been further treated on the merits.

Claim 152 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the embodiment of combining the limitations recited in Claim 77 and Claim 124 in the Claim 152 has not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 77-80, 83-84, 86, 88-89, 92-93, 101-102, 105-111, 113-114, 116-124, 137-140, 142-144 and 152 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Examiner is unable to find a basis of a) the newly introduced component B) recited in Claim 77 or b) "or if either of A and A' is absent, then R₅ and R₆ are independently hydrogen" recited in Claim 84.

Claim Rejections - 35 USC § 102 and 103

8. When the present invention encompasses the embodiment wherein the polyether has a molecular weight of 300 to 700, Claims 77-80, 83-84, 86, 88-89, 101-102, 105-111, 113, 116-121, 122-124, 137-140 and 142-144 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunatillake (WO 99/03863).

Gunatillake discloses a shape memory polyurethane composition as described in paragraph 9 of the previous Office action. Note that the polyether macrodiols can be PHMO that having molecular weights of 696.06 and 700.16 (Examples 2 and 6). Applicant's arguments (Remarks, page 18, second paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. As mentioned above, Gunatillake does disclose a polyether macrodiols having molecular weights of 696.06 and 700.16.

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9. When the present invention encompasses the embodiment wherein the silicon-based macrodiol or silicon-based macrodiamine has a molecular weight of 300 to 700, Claims 77-80, 83-84, 86, 88-89, 101-102, 105-111, 113, 116-124, 137-140 and 142-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunatillake (WO 99/03863).

Gunatillake discloses a shape memory polyurethane composition as described in paragraph 9 of the previous Office action. Applicant's arguments (remarks, page 18, second paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Note that the polysiloxane macrodiol can have a molecular weight of 200 to 5000 (page 10, line 23 to page 11, line 1). Furthermore, the molecular weight of the polysiloxanes macrodiol can be exemplified as 940.27 and 937.83 (Examples 1-2). Therefore, Gunatillake does suggest the use of the lower range of the molecular weight. In addition, the molecular weight of the polysiloxanes macrodiol will affect the properties, such as flexibility, hardness, etc. of the final product. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a polysiloxanes macrodiol having the molecular weight falling within the range claimed by Applicants, through routine experimentation in order to obtain the desired properties. Especially, Applicants do not show the criticality of the claimed molecular weight range. As mentioned in the previous Office action, the properties in Claims 122-124 of the claimed material are Result-Effective variable. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane

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in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

10. Claims 77-80, 83-84, 86, 88-89, 101-102, 105-106, 108-111, 113-114, 117-121, 127-128, 137-140, 142-144, 152 and 154 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito (JP 63-179916).

Ito discloses a shape memory polyurethane composition as described in paragraph 15 of the previous Office action. Applicant's arguments (remarks, page 19, third paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Note that Ito discloses a polyoxy tetramethylene glycol or a polysiloxane diol that can have a molecular weight of 600 to 700 (page 5 of the translation). Applicants indicated that the English translation of JP 63-179916 was not received. Therefore, a copy of it is now re-sending along with this Office action to Applicants.

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11. Claims 77-80, 83-84, 86, 88-89, 101-102, 105-111, 113, 117-121, 137-140, 142-144 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Meijs405 (WO 98/13405).

Meijs405 discloses a shape memory polyurethane composition as described in paragraph 16 of the previous Office action. Applicant's arguments (remarks, page 19, third paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Note that Meijs does teach the use of polyether having a molecular weight falling in the molecular weight range of the present invention (Examples 5, 8, 9, 12, 13, 15, etc.).

12. When the present invention encompasses the embodiment wherein the polyether has a molecular weight of 300 to 700, Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunatillake.

Gunatillake discloses a shape memory polyurethane composition as described in paragraph 8. Applicant's arguments (remarks, page 20, paragraphs 4-6) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. As mentioned in the previous Office action, the properties in Claims 122-124 of the claimed material are Result-Effective variable. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

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13. Claims 77-80, 83-84, 86, 88-89, 101-102, 105, 107, 109-111, 113, 116-121, 137-140, 142-144 and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5 911 737) in view of Gunatillake.

Lee in view of Gunatillake discloses a shape memory polyurethane composition as described in paragraph 19 of the previous Office action. Applicant's arguments (remarks, page 21, second paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Gunatillake discloses a polyurethane composition, *supra*. Furthermore, as mentioned in the previous Office action, the motivation of using Gunatillake's polyurethane based materials is to afford a material which has improved mechanical properties, clarity, processability, biostability and/or degradation resistance (page 13, line 11 to page 15, line 17). In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to use Gunatillake's polyurethane based materials in Lee's disclosure.

14. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito.

Ito discloses a shape memory polyurethane composition, *supra*. Applicant's arguments (remarks, page 22, fourth paragraph to page 23, first paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Note that Ito discloses a polyoxy tetramethylene glycol or a polysiloxane diol that can have a molecular weight of 600 to 700 (page 5 of the translation).

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15. Claims 77, 79-80, 101-102, 109-111, 113, 117-121, 123-124, 128-132 and 154-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US 5 814 705) in view of Gunatillake.

Ward in view of Gunatillake discloses a shape memory polyurethane composition as described in paragraph 25 of the previous Office action. Applicant's arguments (remarks, page 23, third paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Gunatillake discloses a shape memory polyurethane composition, *supra*. Furthermore, as mentioned in the previous Office action, Ward discloses a shape memory polyether urethane used in biomedical applications, and Gunatillake also discloses a shape memory polyether urethane used in biomedical applications. Since Gunatillake's disclosure is in the same field as that of the Ward's endeavor, it would have been obvious to one of ordinary skill in the art at the time of invention to use Gunatillake's polyether urethane in Ward's disclosure with expected success, and thereby obtain the present invention.

16. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs405.

Meijs405 discloses a shape memory polyurethane composition, *supra*. Applicant's arguments (remarks, page 23, fifth paragraph to page 24, second paragraph) have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below. Note that Meijs does teach the use of polyether having a molecular weight falling in the molecular weight range of the present invention (Examples 5, 8, 9, 12, 13, 15, etc.).

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Allowable Subject Matter

17. Claims 95-98 and 153 are allowed.

18. The following is an examiner's statement of reasons for allowance:

None of the aforementioned references teaches or fairly suggest the use of the silicon-based polycarbonate represented by formula (IV) for making a shape memory polyurethane or polyurethane-urea polymer.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

klp
May 28, 2004


Kuo-Liang Peng
Primary Examiner
Art Unit 1712